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Attorney Docket No. 21415-0014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) Ranjeny THOMAS et al.

Confirmation No. 1436

Appl. No.: 10/524,539

Examiner: Unassigned

Filing Date: February 14, 2005

Art Unit: Unassigned

Title: IMMUNOMODULATING COMPOSITIONS, PROCESSES FOR THEIR PRODUCTION AND USES THEREFOR

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

The PTO did not receive the following listed item(s) - none sent NPL's

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RELEVANCE

The relevance of the documents cited on the attached Form SB/08A are described in the present specification.

Document A129 was cited in an earlier Information Disclosure Statement filed by Applicants. Thus, no copy is being provided at this time.

These documents came to the Applicants' attention during a search of the corresponding international application. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached.


TIMING/FEE

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

January 24, 2006  
Date



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Sheet 1 of 12

### Complete if Known

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Filing Date	February 14, 2005
First Named Inventor	Ranjeny THOMAS et al.
Group Art Unit	Unassigned
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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A01	Anton, D., Dabadghao, S., Palucka, K., Hoim, G. & Yi, Q. (1998). Generation of dendritic cells from peripheral blood adherent cells in medium with human serum. <i>Scand J Immunol</i> 47, 116-121	
	A02	Albert ML, Sauter B, Bhardwaj N. (1998). Dendritic cells acquire antigen from apoptotic cells and induce class I-restricted CTLs. <i>Nature</i> 392(6671), 86-89	
	A03	Araki, H., Katayama, N., Mitani, H., Suzuki, H., Nishikawa, H., Masuya, M., Ikuta, Y. Hoshino, N., Miyasluta, H., Nishii, K., Minami, N. & Shiku, H. (2001). Efficient ex vivo generation of dendritic cells from CD14+ blood monocytes in the presence of human serum albumin for use in clinical vaccine trials. <i>Br J Haematol</i> 114, 681-689	
	A04	Ardavin, C., Wu, L., Li, C. L., and Shortman, K. (1993). Thymic dendritic cells and T cells develop simultaneously in the thymus from a common precursor population, <i>Nature</i> 362, 761-763	
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	A06	Baldwin, A. S., Jr. (1996). The NF-kappa B and I kappa B proteins: new discoveries and insights, <i>Annu Rev Immunol</i> 14, 649-683	
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	A09	Battye, F.L. & Shortman, K. (1991). Flow cytometry and cell-separation procedures. [Review]. <i>Curr. Opin. Immunol.</i> 3, 238-241	
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	A11	Bouchon, A., Hernandez-Munain, C., Celia, M., and Colonna, M. (2001b). A DAP12-mediated pathway regulates expression of CC chemokine receptor 7 and maturation of human dendritic cells, <i>J Exp Med</i> 194, 1111-1122	

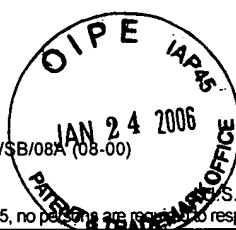
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	A12	Buhlmann, J. E., Foy, T. M., Aruffo, A., Crassi, K. M., Ledbetter, J. A., Green, W. R., Xu, J. C., Shultz, L. D., Roopesian, D., Flavell, R. A., and et al. (1995). In the absence of a CD40 signal, B cells are tolerogenic, <i>Immunity</i> 2, 645-653	
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	A16	Cavanagh LL, Saal RI, Grimmett KL, Thomas R. (1998). Proliferation in monocyte-derived dendritic cell cultures is caused by progenitor cells capable of myeloid differentiation. <i>Blood</i> 92(5), 1598-1607	
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	A18	Chen, B., Stiff P., Sloan, G., Kash, J., Manjunath, R., Pathasarathy, M., Oldenburg, D., Foreman, K.E. & Nickoloff, B.J. (2001). Replicative response, Immunophenotype, and functional activity of monocyte-derived versus CD34(+)-derived dendritic cells following exposure to various expansion and maturational stimuli. <i>Clin Immunol</i> 98, 280-292	
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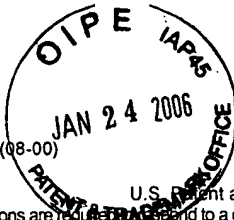
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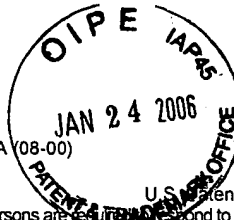
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	A24	de Jong, E. C., Vieira, P. L., Kalinski, P., and Kapsenberg, M. L. (1999) Corticosteroids inhibit the production of inflammatory mediators in immature monocyte-derived DC and induce the development of tolerogenic DC3, J Leukoc Biol 66, 201-204	
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	A27	Diehl, L., Den Boer, A. T., van der Voort, E. I., Melief, C. J., Offringa, R., and Toes, R. E. (2000). The role of CD40 in peripheral T cell tolerance and immunity, J Mol Med 78, 363-371	
	A28	Erickson-Miller, C.L., Brennan, J.K. & Abboud, C.N. (1990). Examination of survival, proliferation and cell surface antigen expression of human monocytes exposed to macrophage colony-stimulating factor (M-CSF). Int J Cell Cloning 8, 346-356	
	A29	Farkas, L., Beiske, K., Lund-Johansen, F., Brandtzaeg, P. & Jahnsen, F.L. (2001). Plasmacytoid Dendritic Cells (Natural Interferon- alpha/beta-Producing Cells) Accumulate in Cutaneous Lupus Erythematosus Lesions. Am J Pathol 159, 237-243	
	A30	Fearnley, D.B., Whyte, L.F., Carnoutsos, S.A., Cook, A.H. & Hart, D.N. (1999). Monitoring human blood dendritic cell numbers in normal individuals and in stem cell transplantation. Blood 93, 728-736	
	A31	Feldmann, M. (2001). Pathogenesis of arthritis: recent research progress, Nat Immunol 2, 771-773	
	A32	Feldmann, M., and Maini, R. N. (2001). Anti-TNFa therapy of rheumatoid arthritis: What have we learned?, Annu Rev Immunol 19, 163-196	
	A33	Feuerstein, B., Berger, T.G., Maczek, C., Roder, C., Schreiner, D., Hirsch, U., Haendle, I., Leisgang, W., Glaser, A., Kuss, O., Diepgen, T.L., Schuler, G. & Schuler-Thumner, B. (2000). A method for the production of cryopreserved aliquots of antigen-preloaded, mature dendritic cells ready for clinical use. J Immunol Methods 245, 15-29	
	A34	Fleming, W.H., Mulcahy, J.M., McKearn, I.P. & Streeter, P.R. (2001). Progenipoietin-l: a multifunctional agonist of the granulocyte colony- stimulating factor receptor and fetal liver tyrosine kinase-3 is a potent mobilizer of hematopoietic stem cells. Exp Hematol 29, 943 - 951	
	A35	Freudenthal, P.S. & Steinman, R.M. (1990). The distinct surface of human blood dendritic cells, as observed after an improved isolation method. Proc Natl Acad Sci U S A 87, 7698-7701	

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	A36	Gao, J. X., Madrenas, J., Zeng, W., Cameron, M. J., Zhang, Z., Wang, I. J., Zhong, It, and Grant, D. (1999). CD40-deficient dendritic cells producing interleukin- 10, but not interleukin- 12, induce T-cell hyporesponsiveness in vitro and prevent acute allograft rejection. <i>Immunology</i> 98, 159-170	
	A37	Garderet, L., Cao, H., Salamero, J., Verge, V., Tisserand, E., Scholl, S., Gorin, N.C. & Lopez, M. 10 (2001). In vitro production of dendritic cells from human blood monocytes for therapeutic use. <i>J Hematother Stem Cell Res</i> 10, 553-567	
	A38	Geissmann, F., Prost, C., Monnet, J.P., Dy, M., Brousse, N. & Hermine, O. (1998). Transforming growth factor beta 1, in the presence of granulocyte/macrophage colony-stimulating factor and interleukin 4, induces differentiation of human peripheral blood monocytes into dendritic Langerhans cells, <i>J Exp Med</i> , 187, 961-966	
	A39	Giannoukakis, N., Bonham, C. A., Qian, S., Zhou, Z., Peng, L., Harnaha, J., Li, W., Thomson, A. W., Fung, 3. J., Robbins, P. D., and Lu, L. (2000). Prolongation of cardiac allograft survival using dendritic cells treated with NP-kB decoy oligodeoxyribonucleotides, <i>Mol Ther</i> 1, 430-437	
	A40	Goodnow, C. C. (2001). Pathways for self-tolerance and the treatment of autoimmune diseases, <i>Lancet</i> 357, 2115-2121	
	A41	Gregori, S., Casorati, M., Amuchastegui, S., Smirolto, S., Davalli, A. M., and Adorri, L. (2001). Regulatory T cells induced by lalpha,25-dihydroxyvitamin d(3) and mycophenolate mofetil treatment mediate transplantation tolerance, <i>J Immunol</i> 167, 1945-1953	
	A42	Griffin, M. D., Lutz, W., Phan, V. A., Bachman, L. A., McKean, D. 3., and Kumar, R. (2001). Dendritic cell modulation by 1 alpha,25 dihydroxyvitamin D3 and its analogs: a vitamin D receptor-dependent pathway that promotes a persistent state of immaturity in vitro and in vivo, <i>Proc Natl Acad Sci USA</i> 98, 6800-6805	
	A43	Groopman, J.E., Mitsuyasu, R.T., DeLeo, M.J., Oette, D.H. & Golde, D.W. (1987). Effect of recombinant human granulocyte-macrophage colony-stimulating factor on myelopoiesis in the acquired immunodeficiency syndrome, <i>N Engl J Med</i> 317, 593-598	
	A44	Grouard, G., Rissoan, MC., Filgueira, L., Durand, I., Banchereau, J. & Liu, Y.J. (1997). The enigmatic plasmacytoid T cells develop into dendritic cells with interleukin (IL)-3 and CD40-ligand <i>J Exp Med</i> 185, 1101-1111	
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	A46	Groux, H., O'Garra, A., Bigler, M., Rouleau, M., Antonenico, S., de Vries, J. E., and Roncarolo, M. G. (1997). A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis, <i>Nature</i> 389, 737-742	
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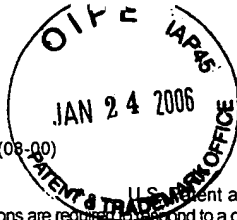
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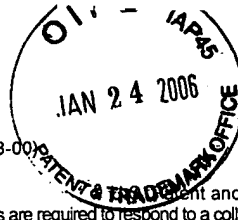
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	A48	Hacker, G., Redecke, V. & Hacker, H. (2002). Activation of the immune system by bacterial CpG-DNA. <i>Immunology</i> 105, 245-251	
	A49	Hackstein, H., Morehi, A. E., Larregina, A. T., Ganster, R. W., Papworth, G. D., Logar, A. I., Watkins, S. C, Falo, L. D., and Thomson, A. W. (2001). Aspirin inhibits in vitro maturation and in vivo immunostimulatory function of murine myeloid dendritic cells, <i>J Immunol</i> 166, 7053-7062	
	A50	Hanninen, A., Martinez, N. R., Davey, G. M., Heath, W. R., and Han'ison, L. C. (2002) Transient blockade of CD40 ligand dissociates pathogenic from protective mucosal immunity, <i>J Clin Invest</i> 109, 261-267	
	A51	Hart DN, Fabre JW. (1981). Demonstration and characterization of Ia-positive dendritic cells in the interstitial connective tissues of rat heart and other tissues, but not brain. <i>J Exp Med</i> 154(2),347-361	
	A52	Hart DN, McKenzie IL. (1988). Isolation and characterization of human tonsil dendritic cells. <i>I Exp Med</i> 168(1), 157-170	
	A53	Hofer, S., Rescigno, M., Granucci, F., Citterio, S., Francolini, M., and Ricciardi-Castagnoli, P. (2001). Differential activation of NP-kappa B subunits in dendritic cells in response to Gram-negative bacteria and to lipopolysaccharide., <i>Microbes Infect</i> 3, 259-265	
	A54	Hill, A.D., Naama, H.A., Calvano, S.E. & Daly, J.M. (1995). The effect of granulocyte macrophage colony-stimulating factor on myeloid cells and its clinical applications. <i>J Leukoc Biol</i> 58, 634-642	
	A55	Hollander, G. A., Castigli, E., Kulbacki, R., Su, M., I\$urakoff, S. J., Gutierrez-Ramos, J. C., and Geha, R. S. (1996). Induction of alloantigen-specific tolerance by B cells from CD40- deficient mice, <i>Proc Natl Acad Sci U S A</i> 93, 4994-4998	
	A56	Huang, F. P., Platt, N., Wykes, M., Major, J. R., Powell, T. J., Jenkins, C. D., and MacPherson, G. G. (2000). A discrete subpopulation of dendritic cells transports apoptotic intestinal epithelial cells to T cell areas of mesenteric lymph nodes, <i>J Exp Med</i> 191,435-444	
	A57	Jonuleit, H., Schmitt, E., Schuler, G., Knop J., and Enk, A. H. (2000). Induction of interleukin 10-producing, non-proliferating CD4 T cells with regulatory properties by repetitive stimulation with allogeneic immature human dendritic cells, <i>J Exp Med</i> 192, 1213-1222	
	A58	Kaisho, T. & Akira. S. (2002). Toll-like receptors as adjuvant receptors. <i>Biochern Biophys Acta</i> 1589, 1-13	
	A59	Kamath, A.T., Pooley, J., O'Keeffe, M.A., Vremec, D., Zhan, Y. Lew, A.M., D'Amico, A., Wu, L., Tough, D.F. & Shortman, K. (2000). The development, maturation, and turnover rate of mouse spleen dendritic cell populations. <i>J Immunol</i> 165, 6762-6770	

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		First Named Inventor	Ranjeny THOMAS et al.
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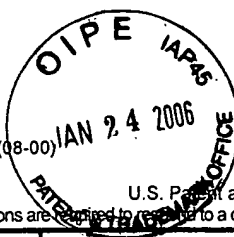
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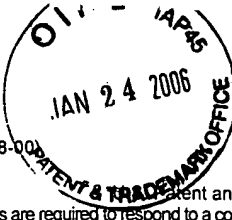
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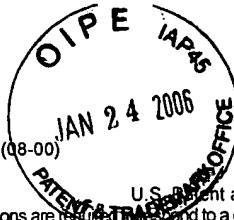
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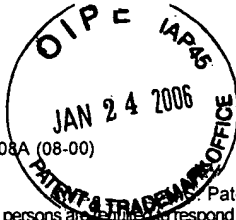
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/524,539
		Filing Date	February 14, 2005
		First Named Inventor	Ranjeny THOMAS et al.
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 12 of 12	Attorney Docket Number	21415-0014US	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A128	Wu, L., A. D. A., Winkel, K. D., Suter, M., Lo, D., and Shortman, K. (1998). RelB is essential for the development of myeloid-related CD8alpha- dendritic cells but not of lymphoid-related CD8alpha+ dendritic cells, <i>Immunity</i> 9, 839-847	
	A129	Yoshimura, S., Bondeson, J., Foxwell, B. M., Brennan, F. M., and Feldmann, M. (2001). Effective antigen presentation by dendritic cells in NF-kappaB dependent coordinate regulation of MHC, costimulatory molecules and cytokines, <i>Int Immunol</i> 13, 675-683	
	A130	Zheng, Z., Takahashi, M., Narita, M., Toba, K., Liu, A., Furukawa, T., Koike, T. & Aizawa, Y. (2000). Generation of dendritic cells from adherent cells of cord blood by culture with granulocyte-macrophage colony-stimulating factor, interleukin-4, and tumor necrosis factor-alpha. <i>J Hematother Stem Cell Res</i> 9, 453-464	
	A131	Zhou, P, and Seder, R. A. (1998). CD40 ligand is not essential for induction of type 1 cytokine responses or protective immunity after primary or secondary infection with histoplasma capsulatum, <i>J Exp Med</i> 187, 1315-1324	

Examiner Signature		Date Considered	
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